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## PATENTS

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/785,681 Confirmation No.: Unassigned  
Applicant: Montalto *et al.*  
Filed: February 24, 2004  
TC/A.AU.: 1614  
Examiner: Unassigned  
  
Docket No.: 07595.105001 SER CON Prions  
Customer No.: 20786  
Title: Process for Inactivating Prions in Lipoproteins

Mail Stop Amendment  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

July 16, 2004

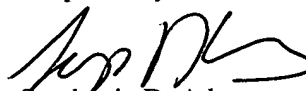
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Respectfully submitted,

  
Stephanie D. Adams  
Reg. No. 47,378

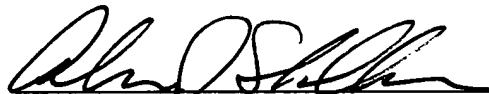
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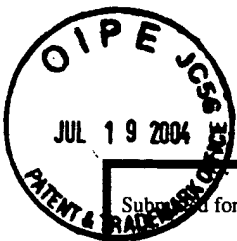
US 10/785,681

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Alicia J. Skillman

Date: July 16, 2004  
07595.105001 CON



<b>Substituted for form 1449/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/785,681
				Filing Date	February 24, 2004
				First Named Inventor	Montalto <i>et al.</i>
				Group Art Unit	Unassigned
				Examiner	Unassigned
Sheet	1	of	3	Attorney Docket Number	07595.105001 SER CON Prions

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U.S. PATENT DOCUMENTS						
Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages / Relevant Figures Appear
		Number	Kind Code (if known)			
	AA	3,112,249	A	Toulmin	11-26-1963	
	AB	4,290,774	A	Girgis <i>et al.</i>	09-22-1981	
	AC	4,762,792	A	Girgis <i>et al.</i>	08-09-1988	
	AD	5,633,349	A	Reichl	05-27-1997	
	AE	5,756,678	A	Shenoy <i>et al.</i>	05-26-1998	
	AF	2003/0032780	A1	Montalto <i>et al.</i>	02-13-2003	

FOREIGN PATENT DOCUMENTS								
Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number	Kind Code <sup>2</sup> (if known)				
	AG	EP	0 742 018	A2	Collagen Corp.	11-13-1996		
	AH	EP	0 937 735	A	Rotkreuzstiftung	08-25-1999		
	AI	WO	02/090379	A1	Serologicals Royalty Co.	11-14-2002		

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	AI	APPEL, T.R., <i>et al.</i> "Heat stability of prion rods and recombinant prion protein in water, lipid and lipid-water mixtures", <i>J. General Virol.</i> 82:465-473 (2001).	
	AJ	BROWN, P., <i>et al.</i> "Newer data on the inactivation of scrapie virus or Creutzfeldt-Jakob disease virus in brain tissue", <i>J. Infect. Dis.</i> , 153(6):1145-1148 (June 1986).	
	AK	BROWN, P., <i>et al.</i> "The distribution of infectivity in blood components and plasma derivatives in experimental models of TSE transfusion," <i>Transfusion</i> , 38(9):810-816 (Sept. 1998).	
	AL	DARBORD, J.C., "Inactivation of prions in daily medical practice," <i>Biomed. &amp; Pharmacother.</i> , 53(1):34-38 (1999).	
	AM	DORMONT, D., "Agents that cause transmissible subacute spongiform encephalopathies," <i>Biomed. &amp; Pharmacother.</i> , 53(1):3-8 (1999).	
	AN	ERNST, D.R., and RACE, R.E., "Comparative analysis of scrapie agent inactivation methods," <i>J. Virol. Methods</i> , 41(2):193-201 (February 1993).	
	AO	FOSTER, P.R., <i>et al.</i> , "Studies on the removal of abnormal prion protein by processes used in the manufacture of human plasma products," <i>Vox Sanguinis</i> , 78(2):86-95 (2000).	
	AP	HORWICH, A.L., & WEISSMAN, J.S., "Deadly conformations -- Protein misfolding in prion disease", <i>Cell</i> , 89:499-510 (May 16, 1997).	

Examiner Signature		Date Con- sidered	
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Submitted for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
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Sheet	2	of	3	Attorney Docket Number	07595.105001 SER CON Prions

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	BA	MASTERTON, Chemical Principles, 4 <sup>th</sup> Ed. (1997), pp. 450, 451, 457.	
	BB	MORGENTHALER, J.-J., "New developments in plasma fractionation and virus inactivation," <i>Vox Sang.</i> , 78(suppl. 2):217-221 (2000).	
	BC	OESCH, B., <i>et al.</i> , "Application of prionics Western blotting procedure to screen for BSE in cattle regularly slaughtered at Swiss abattoirs," <i>Arch. Virol.</i> , 16:189-195 (2000).	
	BD	PARLIAMENTARY OFFICE OF SCIENCE & TECHNOLOGY, "BSE and CJD: Science, Uncertainty and Risk" <i>POST Technical Report</i> (Parliamentary Office of Science & Technology, London), 78:1-12 (April 1996).	
	BE	PL107-9 FEDERAL INTER-AGENCY WORKING GROUP, "Animal disease risk assessment, prevention and control act of 2001. Final report." (January 2003). Listed at <a href="http://www.bna.com/webwatch/madcow.htm">http://www.bna.com/webwatch/madcow.htm</a> , accessed August, 2003.	
	BF	PRUSINER, S.B., <i>et al.</i> , "Thiocyanate and hydroxyl ions inactivate the scrapie agent," <i>Proc. Natl. Acad. Sci. USA</i> , 78(7):4606-4610 (July 1981).	
	BG	SIMONS, K., & EHEHALT, R., "Cholesterols, lipid rafts and disease", <i>J. Clin. Invest.</i> , 110(5):597-603 (September 2002).	
	BH	TAYLOR, D.M., <i>et al.</i> , "Decontamination studies with the agents of bovine spongiform encephalopathy and scrapie," <i>Arch. Virol.</i> , 139(3-4):313-326 (1994).	
	BI	TAYLOR, D.M., "Inactivation of the BSE Agent," <i>J. Food Safety</i> , 18:265-274 (1998).	
	BJ	TAYLOR, D.M., <i>et al.</i> , "Solvent extraction as an adjunct to rendering: The effect on BSE and scrapie agents of hot solvents followed by dry heat and steam," <i>Vet. Record</i> , 143:6-9 (1998).	
	BK	TAYLOR, D.M., "Inactivation of BSE-Like Agents", <i>USAHA Web-- 2001 USAHA Proceedings: Inactivation of BSE-Like Agents</i> (2001), <a href="http://www.usaha.org/speeches/speech01/s01taylo.html">www.usaha.org/speeches/speech01/s01taylo.html</a> , accessed August 8, 2003.	
	BL	UNIVERSITY OF CALIFORNIA AT SAN DIEGO, "Prion Research Guidelines," accessed April 28, 2004 at <a href="http://www.neurosci.ucsd.edu/Safety_Docs/UCSD_Prion_FactSheet.htm">http://www.neurosci.ucsd.edu/Safety_Docs/UCSD_Prion_FactSheet.htm</a> .	
	BM	Von HOLST, C., <i>et al.</i> , "Determination of an appropriate heat treatment of animal waste using the ELISA technique: Results of a validation study," <i>Meat Science</i> , 54:1-7 (2000).	
	BN	WALKER, S.G., <i>et al.</i> , "Aqueous two-phase partition of complex protein feedstocks derived from brain tissue homogenates," <i>J. Chromatography B</i> , 680:91-96 (1990).	
	BO	WORLD HEALTH ORGANIZATION (WHO), "Public health issues related to animal and human spongiform encephalopathies: Memorandum from a WHO meeting," <i>Bulletin of the World Health Organization</i> , 70(2):183-190 (1992). [Meeting in Geneva, Switzerland, 12-14 November 1991, World Health Organization 1992, WHO/CDS/VPH/92.104, 19 pages.]	

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	BP	Recommendations for Minimizing the Risk of Infection by Agents Causing Zoonoses and Other Animal Infections in the Manufacture of Medicinal Products, Federal Journal of Official Publications (BAnz., Germany), No. 164, p. 6120 (1991).	

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